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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,661	04/21/2004	Raymond A. McClanahan	MCL-2.001.US	4929

22874 7590 07/20/2007
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EXAMINER

LEWIS, KIM M

ART UNIT	PAPER NUMBER
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3772

MAIL DATE	DELIVERY MODE
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07/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/828,661

Applicant(s)

MCCLANAHAN ET AL.

Examiner

Kim M. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☒ Other: Detailed Action.

DETAILED ACTION

Response to Amendment

1. The amendment under 37 CFR 1.132 filed 4/16/07 has been received and made of record. As requested, claims 1, 2, 15, 17 and 27-29 have been amended. Claim 16 has been canceled.
2. Claims 1-15 and 17-30 are pending in the instant application.

Allowable Subject Matter

3. The indicated allowability of claims 4-14 and 2, 17-26, 28 and 29 is withdrawn in view of the newly discovered reference(s) to Arrowsmith, Scholl and Wall. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 1,103,465 ("Arrowsmith").

As regards claim 1, Arrowsmith discloses a bunion shield and corrector that anticipates applicant's orthotic toe spacer as presently claimed. More specifically, Arrowsmith discloses two or more inter-digital columns (B, C) for extending generally

vertically between adjacent toes of a user, each column being independently width-adjustable by filling them with absorbent cotton to form an orthotic spacer for urging laterally apart the adjacent toes that the column extends between to a defined inter-digital spacing (page 1, lines 36-57).

As regards claim 2, Arrowsmith disclose an orthotic toe spacer (constituted by the bunion shield and corrector comprising: an inter-digital column (B,C) for extending generally vertically, between adjacent toes of a user, the column being width-adjustable to form an orthotic spacer for urging laterally apart the adjacent toes that the column extends between to a defined inter-digital spacing, and wherein the column includes a width-adjustable recess therein for receiving an insert of defined width to fix the inter-digital spacing) page 1, lines 40-57).

6. Claims 1, 4, 8, 9, 15, 17, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 853,327 ("Wall").

As regards claim 1, Wall discloses a bunion shield and corrector that anticipates applicant's orthotic toe spacer as presently claimed. More specifically, Wall discloses two or more inter-digital columns (10, 11) for extending generally vertically between adjacent toes of a user, each column being independently width-adjustable by filling them with absorbent cotton to form an orthotic spacer for urging laterally apart the adjacent toes that the column extends between to a defined inter-digital spacing (page 1, lines 94-107 and page 2, lines 7-13).

As regards claim 4, Wall discloses an orthotic toe spacer (constituted by the spreader) comprising: an inter-digital column (10, 11) for extending generally vertically

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between adjacent toes of a user, the column having a generally cylindrical hour-glass shape (when placed between the user's toes) including cross-sectionally concave sidewalls; a hollow elongate generally planar recess formed in a generally central region of the column; and an insert fitted into the recess and fixedly gripped thereby, the Insert iridizing the column and laterally widening the recess and the column into which the insert is fitted (page 1, lines 103-107); the column having the insert within the recess forming an orthotic spacer for urging laterally apart the adjacent toes that the spacer extends between to a predetermined inter-digital spacing (page 1, lines 103-107).

As regards claims 8 and 9, Wall discloses the columns are constructed from rubber, an elastomeric polymer.

As regards claims 15 and 17, Wall discloses an orthotic foot platform apparatus (constituted by the toe spreader) comprising: two or more inter-digital spacers (10, 11) for extending between one or more pairs of adjacent toes, each of the two or more spacers being independently width-adjustable and made of a material that is shape-retentive during use and sufficiently durable to urge apart and maintain a predetermined separation between adjacent toes of the one or more pairs (applicant should note that they are made out of pliable rubber), each of the spacers having upper and lower generally parallel planar regions (note Fig. 7), and one or more interconnecting web structures (9, 11) fixedly attached to and extending across the upper and lower regions of the two or more spacers to fix the spacers relative to one another in a generally parallel configuration to produce a toe channel between the two or more spacers for receiving one of the two or more adjacent toes and for spacing apart at least one other

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of the one or more pairs of adjacent toe, and wherein each of the spacers includes a recess therein extending inwardly from at least one of the upper and lower regions, which apparatus further comprises: one or more inserts (12) within the one or more recesses, the inserts configured to rigidize the spacers and the inserts dimensioned to widen the recess and the column thereby to fix inter-digital spacing between the adjacent toes of the one or more pairs (page 1, lines 10-106).

As regards claim 27, Wall discloses an orthotic foot care method by mere use of the toe spreader. The method comprises fitting a foot of a user with an appliance having two or more spacers (10, 11) for extending between pairs of adjacent toes and for spreading the same relative to one another, and independently adjusting the width of individual ones of such spacers to a desired spacing for each pair of adjacent toes on the foot of the user (by inserting a filling in to the spacers).

As regards claim 28, Wall discloses the method of claim 27 by mere use of the toe spreader. The method comprises fitting a foot of a user with an appliance (the toe spreader) having spacers (10, 11) for extending between pairs of adjacent toes and for spreading the same relative to one another, and adjusting the width of individual ones of such spacers to a desired spacing for each pair of adjacent toes on the foot of the user, and wherein the adjusting includes selecting and inserting shims of predetermined width into corresponding recesses formed within the bodies of the spacers (page 1, lines 10-107 and page 2, lines 7-13).

7. Claims 4, 6, 10, 12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 1,080,304 ("Scholl").

As regards claim 4, Wall discloses an orthotic toe spacer (constituted by the spreader) comprising: an inter-digital column (12) for extending generally vertically between adjacent toes of a user, the column having a generally cylindrical hour-glass shape (Fig. 4) including cross-sectionally concave sidewalls; a hollow elongate generally planar recess formed in a generally central region of the column; and an insert (16a, 16b) fitted into the recess and fixedly gripped thereby, the insert rigidizing the column and laterally widening the recess and the column into which the insert is fitted (page 1, lines 78-88); the column having the insert within the recess forming an orthotic spacer for urging laterally apart the adjacent toes that the spacer extends between to a predetermined inter-digital spacing (page 1, lines 78-93).

As regards claim 6, Scholl discloses the spacer of claim 4, wherein the insert is a pressure-adjustable pneumatic bladder (page 1, lines 85-86).

Regarding claim 10, as can be seen from Fig. 1, Scholl discloses the spacer of claim 4, wherein the column is elongated for extending along an axis between the adjacent toes and wherein the column is dimensioned in length approximately equal to the average length of the adjacent toes.

Regarding claim 12, as can be seen from Fig. 4, Scholl discloses the spacer of claim 4, wherein the recess extends through the column from a top region to a bottom region of the column.

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As regards claim 14, Scholl discloses the spacer of claim 4, which further comprises: a fastener for attaching to the foot of the user the column with the insert therein (note anchoring structure 20, 21 and page 1, lines 103-109).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 3, 5, 11, 13, 18-25 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wall.

As regards claim 3, Wall discloses the spacer of claim 1, except wherein the column includes a width-adjustable, pressurizable bladder for receiving a fluid under pressure to fix the inter-digital spacing. Instead, Wall discloses that the column itself can be converted into a pressurizable bladder. It would have been obvious to one having ordinary skill in the art to modify the teaching of converting the tube into a pressurizable bladder to including providing a pressurizable bladder insert in order so that the inserts can be varied as desired. See for example, U.S. Patent No. 1,080,304, which discloses a separate pressurizable bladder 16b as an insert.

As regards claim 5, Wall discloses the spacer of claim 4, except wherein the recess is dimensioned to accommodate therein an insert in the form of a shim selected from a group of shims of various widths. Instead, Wall discloses the insert may be cotton (page 1, lines 103-107) or suitable matter (page 2, lines 7-11).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide different sized pieces of cotton or suitable matter (shims) in order to vary the degree of rigidity as needed.

Regarding claims 11 and 13, Wall does not disclose the particular shape of the insert, *i.e.*, fails to teach that the insert is of a generally circular disk shape having opposing tabs extending radially from the center and fails to teach the recess is of a

generally circular disk shape and wherein the insert is of a generally circular disk shape, wherein the recess and the insert are generally isometric and isomorphic to one another. However, the cotton filling material, once inserted in the tube, will take the form of tube. As to the tabs, one having ordinary skill in the art would have found it *prima facie* obvious to add tabs to the insert in order to allow for easy removal of the insert from the tube.

As regards claim 18, Wall discloses the apparatus of claim 17, except wherein the apparatus comprises four of the spacers having four recesses therein and four of the inserts within the four recesses. It would have been obvious to one having ordinary skill in the art at the time the invention was made to add additional spacers to fit between additional toes, since it has been held that the mere duplication of essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.* 193 USPQ 8.

With respect to claim 19, the limitation "wherein the four spacers and the one or more web structures are formed together by integrally molding the same", is not given patentable weight since the method of forming the device is not germane to the issue of patentability of the device itself.

With respect to claim 20, Wall discloses the tubes are constructed from pliable rubber, thereby being elastomeric material. It then follows that additional tubes would also be made from the same elastomeric material.

With respect to claim 21, Wall fails to teach that the inserts are formed of an elastomeric material having a defined width that fixes a desired inter-digital spacing.

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Wall discloses cotton or other suitable matter as the material for the insert. It would have been obvious to one having ordinary skill in the art to modify the material of the insert to include an elastomeric material, since it has been held that the selection of a known material based upon its suitability is a design consideration within the level of ordinary skill in the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

With respect to claim 22, Wall discloses the apparatus of claim 20, except wherein the inserts include an adjustably pressurizable bladder having a defined width that fixes a desired inter-digital spacing. Instead, Wall discloses that the column itself can be converted into a pressurizable bladder. It would have been obvious to one having ordinary skill in the art to modify the teaching of converting the tube into a pressurizable bladder to including providing a pressurizable bladder insert in order so that the inserts can be varied as desired. See for example, U.S. Patent No. 1,080,304, which discloses a separate pressurizable bladder 16b as an insert.

With respect to claim 23, once modified to include the four spacers, the spacers will be adhered (connected) at the respective upper and lower regions thereof to the one or more web structures.

As regards claim 24, Wall discloses the apparatus of claim 23, wherein the one or more web structures are curved in an arc conforming to an arc of the toes during use and fix the four spacers in an arc corresponding thereto during use.

As regards claim 25, Wall discloses the apparatus of claim 24, wherein the four recesses extend through the four columns from the top region toward the bottom region

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thereof, and wherein the four recesses are dimensioned to accommodate therein shims selected from a group of shims of various widths.

As to method claim 29, Wall discloses the inherent method as presently claimed including the steps of fitting a foot of a user with an appliance having spacers (10, 11) for extending between pairs of adjacent toes and for spreading the same relative to one another, and adjusting the width of individual ones of such spacers to a desired spacing for each pair of adjacent toes on the foot of the user. Wall fails to teach wherein the adjusting includes selecting and inserting pressurizable bladders of adjustable width into corresponding recesses formed within the bodies of the spacers. Instead, Wall discloses that the column itself can be converted into a pressurizable bladder. It would have been obvious to one having ordinary skill in the art to modify the teaching of converting the tube into a pressurizable bladder to including providing a pressurizable bladder insert in order so that the inserts can be varied as desired. See for example, U.S. Patent No. 1,080,304, which discloses a separate pressurizable bladder 16b as an insert.

12. Claims 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scholl.

As regards claim 7, Scholl discloses the spacer of claim 4, wherein the insert is a pressure-adjustable pneumatic cushion. Scholl fails to disclose a hydraulic bladder. It would have been obvious to one having ordinary skill in the art at the time the invention

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was made to substitute the pneumatic cushion of Scholl for a hydraulic cushion or bladder since they perform the same function of rigidifying the column.

13. Claims 26 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wall in view of Scholl.

As regards claim 26, as modified Wall discloses apparatus of claim 23 except a fastener for attaching to the foot of the user the integrally molded web structures and spacers having the four inserts therein. Scholl, however, discloses a fastener (20, 21) in order to maintain the device in position. In view of Scholl, it would have been obvious to one having ordinary skill in the art to provide the device of Wall with a fastener in order to help maintain the device in position between the toes.

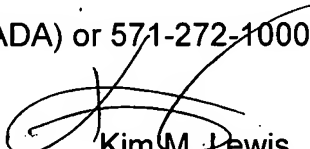
As regards claim 30, Wall fails to teach fastening the device to the foot. Scholl, however, discloses an orthotic foot care device in the form of a toe spreader and inherent method of use, having a fastening mechanism (20, 21) to help maintain the spreader in position between the toes. In view Scholl, it would have been obvious to one having ordinary skill in the art to modify Wall with the addition of a fastener mechanism in order to fasten the device to the foot to maintain the device in position between the toes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-4796. The examiner can normally be reached on Monday to Friday, from 8:30 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco, can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Kim M. Lewis
Primary Examiner
Art Unit 3772

kml
July 12, 2007